



CERTIFICATE OF MAILING UNDER 37 C.F.R. §1.8

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail, with sufficient postage, in an envelope addressed to: Mail Stop Amendment; Commissioner for Patents, P. O. Box 1450, Alexandria, VA 22313-1450, on the below date:
Date: August 2, 2006 Name: Heidi A. Dare, Reg. No. 50,775 Signature: Heidi A. Dare

BRINKS
HOFFER
GILSON
& LIONE

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Appln. of: Claudia Lange et al.

Appln. No.: 10/575,961

Filed: April 13, 2006

For: Blood Products from Mesenchymal Stem Cells

Examiner: To Be Assigned

Art Unit: To Be Assigned

Attorney Docket No: 12103-9

Mail Stop Amendment
Commissioner for Patents
P. O. Box 1450
Alexandria, VA 22313-1450

TRANSMITTAL

Sir:

Attached is/are:

- ☒ Information Disclosure Statement; Form PTO-1449; copies of references A4-A30
☒ Return Receipt Postcard

Fee calculation:

- ☒ No additional fee is required.
☐ Small Entity.
☐ An extension fee in an amount of \$_____ for a _____-month extension of time under 37 C.F.R. § 1.136(a).
☐ A petition or processing fee in an amount of \$_____ under 37 C.F.R. § 1.17(____).
☐ An additional filing fee has been calculated as shown below:

| | | | | | Small Entity | | | Not a Small Entity | |
|---|-------------------------------------|-------|------------------------------------|------------------|--------------|-----------|----|--------------------|-----------|
| | Claims Remaining After Amendment | | Highest No. Previously Paid For | Present Extra | Rate | Add'l Fee | or | Rate | Add'l Fee |
| Total | | Minus | | | x \$25= | | | x \$50= | |
| Indep. | | Minus | | | x 100= | | | x \$200= | |
| First Presentation of Multiple Dep. Claim | | | | | + \$180= | | | + \$360= | |
| | | | | | Total | \$ | | Total | \$0 |

Fee payment:

- ☐ A check in the amount of \$_____ is enclosed.
☐ Please charge Deposit Account No. 23-1925 in the amount of \$_____. A copy of this Transmittal is enclosed for this purpose.
☐ Payment by credit card in the amount of \$_____ (Form PTO-2038 is attached).
☒ The Director is hereby authorized to charge payment of any additional filing fees required under 37 CFR § 1.16 and any patent application processing fees under 37 CFR § 1.17 associated with this paper (including any extension fee required to ensure that this paper is timely filed), or to credit any overpayment, to Deposit Account No. 23-1925.

Respectfully submitted,

August 2, 2006
Date

Heidi A. Dare
Heidi A. Dare (Reg. No. 50,775)

BRINKS HOFFER GILSON & LIONE

NBC Tower – Suite 3600, 455 N. Cityfront Plaza Drive, Chicago, IL 60611-5599

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INFORMATION DISCLOSURE STATEMENT

In accordance with the duty of disclosure under 37 C.F.R. §1.56 and §§1.97-1.98, and more particularly in accordance with 37 C.F.R. §1.97(b), Applicants hereby cite the following references:

| No. | Date | Applicant or Country (if foreign) |
|--|---------|--------------------------------------|
| 2002-0064519 A1 | 05/2002 | Bruder et al. |
| 5,736,396 | 04/1998 | Bruder et al. |
| 5,942,225 | 08/1999 | Bruder et al. |
| WO 99/61588 A1 | 12/1999 | WIPO |
| WO 03/070922 A1 | 08/2003 | WIPO |
| WO 05/015151 A2 | 02/2005 | WIPO |
| WO 05/042019 A1 | 05/2005 | WIPO |
| Deng et al., "In Vitro Differentiation of Human Marrow Stromal Cells into Early Progenitors of Neural Cells by Conditions That Increase Intracellular Cyclic AMP;" 2001, <i>Biochem. Biophys. Res. Commun.</i> , 282(1):148-52. | | |
| Drouet, M. et al.; "Mesenchymal stem cells rescue CD34+ cells from radiation-induced apoptosis and sustain hematopoietic reconstitution after coculture and cograftering in lethally irradiated baboons: is autologous stem cell therapy in nuclear accident settings hype or reality?;" Bone Marrow Transplant; 2005 June; 35(12):1201-9. Abstract. | | |
| Fukuda, K, 2001, <i>Artif. Organs</i> , 25(3):187-93. | | |
| Graca Almeida-Porada, M. et al.; "[3292] Clonally Derived Marrow Stromal Cells (MSC) Populations Are Able to Differentiate into Blood, Liver, and Skin Cells;" American Society of Hematology 43 rd Annual Meeting and Exposition, December 7-11, 2001, Orlando, Florida. Abstract. | | |
| Graca Almeida-Porada, M. et al.; "[2979] Human Marrow Stromal Cells (MSC) Represent a Latent Pool of Stem Cells Capable of Generating Long-Term Hematopoietic Cells;" American Society of Hematology 43 rd Annual Meeting and Exposition, December 7-11, 2001, Orlando, Florida. Abstract. | | |
| Graca Almeida-Porada, M. et al.; "A large animal noninjury model for study of human stem cell plasticity;" Blood Cells, Molecules, and Diseases 32 (2004) 77-81. | | |

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| Hofstetter, C.P. et al.; "Marrow stromal cells from guiding strands in the injured spinal cord and promote recovery," PNAS, vol. 99, no. 4; February 19, 2002; 2199-2204. |
| Huss, R. et al.; "Evidence of Peripheral Blood-Derived, Plastic-Adherent CD34 ^{low} Hematopoietic Stem Cell Clones with Mesenchymal Stem Cell Characteristics," Stem Cells 2000;18:252-260. |
| Hu, Ying et al: "Transplantation of mesenchymal stem cells followed by G-CSF injection can reconstitute hematopoiesis of lethally irradiated BALB/C mice" Blood, vol. 98, no. 11 Part 2, 16 November 2001(2001-11-16), page 316b, XP009042610 & 43rd Annual Meeting Of The American Society Of Hematology, Part 2; Orlando, Florida, USA; December 07-11, 2001 ISSN: 0006-4971. Abstract. |
| Jaiswal, N et al., 1997, <i>J. Cell Biochem.</i> , 64(2):295-312. |
| Jiang Yehua et al.: "Pluripotency of mesenchymal stem cells dreived from adult marrow" Nature (London), vol. 418, no. 6893, 4 July 2002 (2002-07-04), pages 41-49, XP001204372 ISSN: 0028-0836. |
| Lange, C. et al.; "Hematopoietic Reconstitution of Syngeneic Mice with a Peripheral Blood-Derived, Monoclonal CD34 ⁺ , Sca-1 ⁺ , Thy-1 ^{low} , c-kit ⁺ Stem Cell Line," Journal of Hematotherapy & Stem Cell Research 8:335-342 (1999). |
| Mourcin, F. et al.; "Mesenchymal Stem Cells Support Expansion of In Vitro Irradiated CD34(+) Cells in the Presence of SCF, FLT3 Ligand, TPO and IL3: Potential Application to Autologous Cell Therapy in Accidentally Irradiated Victims," 1: Radiat Res.; 2005 Jul; 164(1):1-9. Abstract. |
| Osawa M. et al: "Long-term lymphohematopoietic reconstitution by a single CD34 low/negative hematopoietic stem cell" Science, American Association For The Advancement Of Science, US, vol. 273, no. 5272, 12 July 1996 (1996-07-12), pages 242-245, XP002097289 ISSN: 0036-8075. |
| Pei X: "Who is hematopoietic stem cell: CD34+ or CD34-?" International Journal Of Hematology Dec 1999, vol. 70, no. 4, December 1999 (1999-12), pages 213-215, XP009042521 ISSN: 0925-5710. |
| Pei Xuetao: "Stem cell engineering: The new generation of cellular therapeutics" International Journal Of Hematology Suppl. I, vol. 76, August 2002 (2002-08), pages 155-156, XP009042425. Abstract. |
| Pittenger, MF et al., Science. 1999 Apr 2;284(5411):143-7. |
| Reyes Morayma et al: "Origin of endothelial progenitors in human post-natal bone marrow" Blood, vol. 98, no. 11 Part 1, 16 November 2001 (2001-11-16), page 821a, XP002313288 & 43rd Annual Meeting Of The American Society Of Hematology, Part 1; Orlando, Florida, USA; December 07-11, 2001 ISSN: 0006-4971. Abstract. |
| Shakibaei, M et al., 1997, <i>Cell Biol. Int.</i> , 21(2):115-25 |
| Thierry, D. et al.; "Cell therapy for the treatment of accidental radiation overexposure," 1: BJR Suppl. 2005; 27:175-9. |
| Toma, C et al., 2002, <i>Circulation</i> , 105(1):93-8. |
| Woodbury et al., 2000, <i>J. Neurosci. Res.</i> , 61(4):364-70. |
| Zhao Z. et al.; "Establishment and properties of fetal dermis-derived mesenchymal stem cell lines: plasticity in vitro and hematopoietic protection in vivo," 1: Bone Marrow Transplant; 2005 Jun 20; [Epub ahead of print]. Abstract. |

Applicants are enclosing Form PTO-1449 (three sheets), along with a copy of each listed reference for which a copy is required under 37 C.F.R. §1.98(a)(2). As each

of the listed references is in English, no further commentary is believed to be necessary, 37 C.F.R §1.98(a)(3). Applicants respectfully request the Examiner's consideration of the above references and entry thereof into the record of this application.

By submitting this Statement, Applicants are attempting to fully comply with the duty of candor and good faith mandated by 37 C.F.R. §1.56. As such, this Statement is not intended to constitute an admission that any of the enclosed references, or other information referred to therein, constitutes "prior art" or is otherwise "material to patentability," as that phrase is defined in 37 C.F.R. §1.56(a).

Applicants have calculated no fee to be due in connection with the filing of this Statement. However, the Director is authorized to charge any fee deficiency associated with the filing of this Statement to a deposit account, as authorized in the Transmittal accompanying this Statement.

Respectfully submitted,

August 2, 2006
Date

Heidi A. Dare
Heidi A. Dare (Reg. No. 50,775)



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|---|-------------------------------|----------------------------------|
| FORM PTO-1449 | SERIAL NO. 10/575,961 | CASE NO. 12103-9 |
| LIST OF PATENTS AND PUBLICATIONS FOR APPLICANT'S INFORMATION DISCLOSURE STATEMENT | FILING DATE April 13, 2006 | GROUP ART UNIT To Be Assigned |
| (use several sheets if necessary) | | APPLICANTS: Claudia Lange et al. |

REFERENCE DESIGNATION

U.S. PATENT DOCUMENTS

| EXAMINER INITIAL | | DOCUMENT NUMBER <small>Number-Kind Code (if known)</small> | DATE | NAME | CLASS/ SUBCLASS | FILING DATE |
|---------------------|----|--|---------|---------------|--------------------|----------------|
| | A1 | 2002-0064519 A1 | 05/2002 | Bruder et al. | | |
| | A2 | 5,736,396 | 04/1998 | Bruder et al. | | |
| | A3 | 5,942,225 | 08/1999 | Bruder et al. | | |
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FOREIGN PATENT DOCUMENTS

| EXAMINER INITIAL | | DOCUMENT NUMBER <small>Number-Kind Code (if known)</small> | DATE | COUNTRY | CLASS/ SUBCLASS | TRANSLATION YES OR NO |
|---------------------|----|--|---------|---------|--------------------|--------------------------|
| | A4 | WO 99/61588 A1 | 12/1999 | WIPO | | |
| | A5 | WO 03/070922 A1 | 08/2003 | WIPO | | |
| | A6 | WO 05/015151 A2 | 02/2005 | WIPO | | Yes (Abstract) |
| | A7 | WO 05/042019 A1 | 05/2005 | WIPO | | |
| | | | | | | |

| EXAMINER INITIAL | OTHER ART – NON PATENT LITERATURE DOCUMENTS <small>(Include name of author, title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date page(s), volume-issue number(s), publisher, city and/or country where published.</small> | |
|---------------------|--|--|
| | A8 | Deng et al., "In Vitro Differentiation of Human Marrow Stromal Cells into Early Progenitors of Neural Cells by Conditions That Increase Intracellular Cyclic AMP;" 2001, <i>Biochem. Biophys. Res. Commun.</i> , 282(1):148-52. |
| | A9 | Drouet, M. et al.; "Mesenchymal stem cells rescue CD34+ cells from radiation-induced apoptosis and sustain hematopoietic reconstitution after coculture and cograftering in lethally irradiated baboons: is autologous stem cell therapy in nuclear accident settings hype or reality?;" Bone Marrow Transplant; 2005 June; 35(12):1201-9. Abstract. |
| | A10 | Fukuda, K, 2001, <i>Artif. Organs</i> , 25(3):187-93. |
| | A11 | Graca Almeida-Porada, M. et al.; "[3292] Clonally Derived Marrow Stromal Cells (MSC) Populations Are Able to Differentiate into Blood, Liver, and Skin Cells"; American Society of Hematology 43 rd Annual Meeting and Exposition, December 7-11, 2001, Orlando, Florida. Abstract. |
| | A12 | Graca Almeida-Porada, M. et al.; "[2979] Human Marrow Stromal Cells (MSC) Represent a Latent Pool of Stem Cells Capable of Generating Long-Term Hematopoietic Cells;" American Society of Hematology 43 rd Annual Meeting and Exposition, December 7-11, 2001, Orlando, Florida. Abstract. |
| EXAMINER | | DATE CONSIDERED |

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

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|---|-------------------------------|----------------------------------|
| FORM PTO-1449 | SERIAL NO. 10/575,961 | CASE NO. 12103-9 |
| LIST OF PATENTS AND PUBLICATIONS FOR APPLICANT'S INFORMATION DISCLOSURE STATEMENT | FILING DATE April 13, 2006 | GROUP ART UNIT To Be Assigned |
| (use several sheets if necessary) | | APPLICANTS: Claudia Lange et al. |

| EXAMINER INITIAL | OTHER ART – NON PATENT LITERATURE DOCUMENTS (Include name of author, title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date page(s), volume-issue number(s), publisher, city and/or country where published. | |
|---------------------|---|---|
| | A13 | Graca Almeida-Porada, M. et al.; "A large animal noninjury model for study of human stem cell plasticity," Blood Cells, Molecules, and Diseases 32 (2004) 77-81. |
| | A14 | Hofstetter, C.P. et al.; "Marrow stromal cells from guiding strands in the injured spinal cord and promote recovery," PNAS, vol. 99, no. 4; February 19, 2002; 2199-2204. |
| | A15 | Huss, R. et al.; "Evidence of Peripheral Blood-Derived, Plastic-Adherent CD34 ^{low} Hematopoietic Stem Cell Clones with Mesenchymal Stem Cell Characteristics," Stem Cells 2000;18:252-260. |
| | A16 | Hu, Ying et al: "Transplantation of mesenchymal stem cells followed by G-CSF injection can reconstitute hematopoiesis of lethally irradiated BALB/C mice" Blood, vol. 98, no. 11 Part 2, 16 November 2001(2001-11-16), page 316b, XP009042610 & 43rd Annual Meeting Of The American Society Of Hematology, Part 2; Orlando, Florida, USA; December 07-11, 2001 ISSN: 0006-4971. Abstract. |
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| | A19 | Lange, C. et al.; "Hematopoietic Reconstitution of Syngeneic Mice with a Peripheral Blood-Derived, Monoclonal CD34 ⁺ , Sca-1 ⁺ , Thy-1 ^{low} , c-kit ⁺ Stem Cell Line," Journal of Hematotherapy & Stem Cell Research 8:335-342 (1999). |
| | A20 | Mourcin, F. et al.; "Mesenchymal Stem Cells Support Expansion of In Vitro Irradiated CD34(+) Cells in the Presence of SCF, FLT3 Ligand, TPO and IL3: Potential Application to Autologous Cell Therapy in Accidentally Irradiated Victims;" 1: Radiat Res.; 2005 Jul; 164(1):1-9. Abstract. |
| | A21 | Osawa M. et al: "Long-term lymphohematopoietic reconstitution by a single CD34 low/negative hematopoietic stem cell" Science, American Association For The Advancement Of Science, US, vol. 273, no. 5272, 12 July 1996 (1996-07-12), pages 242-245, XP002097289 ISSN: 0036-8075. |
| | A22 | Pei X: "Who is hematopoietic stem cell: CD34+ or CD34-?" International Journal Of Hematology Dec 1999, vol. 70, no. 4, December 1999 (1999-12), pages 213-215, XP009042521 ISSN: 0925-5710. |
| | A23 | Pei Xuetao: "Stem cell engineering: The new generation of cellular therapeutics" International Journal Of Hematology Suppl. I, vol. 76, August 2002 (2002-08), pages 155-156, XP009042425. Abstract. |
| | A24 | Pittenger, MF et al., Science. 1999 Apr 2;284(5411):143-7. |
| | A25 | Reyes Morayma et al: "Origin of endothelial progenitors in human post-natal bone marrow" Blood, vol. 98, no. 11 Part 1, 16 November 2001 (2001-11-16), page 821a, XP002313288 & 43rd Annual Meeting Of The American Society Of Hematology, Part 1; Orlando, Florida, USA; December 07-11, 2001 ISSN: 0006-4971. Abstract. |
| | A26 | Shakibaei, M et al., 1997, <i>Cell Biol. Int.</i> , 21(2):115-25 |

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| | A27 | Thierry, D. et al.; "Cell therapy for the treatment of accidental radiation overexposure;" 1: BJR Suppl. 2005; 27:175-9. |
| | A28 | Toma, C et al., 2002, Circulation, 105(1):93-8. |
| | A29 | Woodbury et al., 2000, J. Neurosci. Res., 61(4):364-70. |
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